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| APPLICATION NO. | | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------|---------|-------------|-------------------------|------------------------------|------------------|--|
| 10/026,106 | | 12/21/2001 | Jean-Christophe Renauld | LUD 5752 DIV JEL/NDH (101 | | |
| 24972 | 7590 | 08/04/2004 | | EXAMINER | | |
| FULBRIGE | | WORSKI, LLP | HAMUD, FOZIA M | | | |
| NEW YORK | K, NY 1 | 0103-3198 | | ART UNIT | PAPER NUMBER | |
| | | | | 1647 | | |

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | |
|--|---|--|---|
| Advisory Action | 10/026,106 | RENAULD ET AL. | |
| | Examiner | Art Unit | |
| | Fozia M Hamud | 1647 | |
| The MAILING DATE of this communication appe | ears on the cover sheet with the c | orrespondence add | ress |
| THE REPLY FILED 18 May 2004 FAILS TO PLACE THIS Therefore, further action by the applicant is required to average final rejection under 37 CFR 1.113 may only be either: (1) condition for allowance; (2) a timely filed Notice of Appeal Examination (RCE) in compliance with 37 CFR 1.114. | oid abandonment of this application and indication of the application | ation. A proper reply n places the applica | y to a ition in |
| PERIOD FOR RE | EPLY [check either a) or b)] | | |
| a) The period for reply expires 3 months from the mailing date b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire I ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The fee have been filed is the date for purposes of determining the period of fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of (2) as set forth in (b) above, if checked. Any reply received by the Office timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.17(a) is calculated from: (1) the expiration date of (2) as set forth in (b) above, if checked. Any reply received by the Office timely filed, may reduce any earned patent term adjustment. | Advisory Action, or (2) the date set forth ater than SIX MONTHS from the mailing FILED WITHIN TWO MONTHS OF THE date on which the petition under 37 CFI extension and the corresponding amount the shortened statutory period for reply one later than three months after the mail | g date of the final rejection HE FINAL REJECTION. R 1.136(a) and the apprount of the fee. The appropriate in the final i | on. See MPEP opriate extension opriate extension Office action: or |
| 1. A Notice of Appeal was filed on Appellant's 37 CFR 1.192(a), or any extension thereof (37 CFF | R 1.191(d)), to avoid dismissal of | riod set forth in f the appeal. | |
| 2. The proposed amendment(s) will not be entered be | ecause: | | |
| (a) they raise new issues that would require further | er consideration and/or search (s | see NOTE below); | |
| (b) they raise the issue of new matter (see Note b | elow); | | |
| (c) they are not deemed to place the application in issues for appeal; and/or | n better form for appeal by mater | rially reducing or sin | nplifying the |
| (d) they present additional claims without canceling | ng a corresponding number of fi | nally rejected claim: | S. |
| NOTE: | | | |
| $3. \boxtimes$ Applicant's reply has overcome the following reject | ion(s): See Continuation Sheet. | | |
| 4. Newly proposed or amended claim(s) would canceling the non-allowable claim(s). | be allowable if submitted in a se | parate, timely filed | amendment |
| 5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for application in condition for allowance because: | reconsideration has been consideration. | dered but does NO | Γ place the |
| 6. The affidavit or exhibit will NOT be considered becaraised by the Examiner in the final rejection. | ause it is not directed SOLELY to | o issues which were | enewly |
| 7. For purposes of Appeal, the proposed amendments explanation of how the new or amended claims we | | | nd an |
| The status of the claim(s) is (or will be) as follows: | | | |
| Claim(s) allowed: | | | |
| Claim(s) objected to: | | | |
| Claim(s) rejected: <u>1-12,24,25 and 29</u> . | | | |
| Claim(s) withdrawn from consideration: | | | |
| 8. The drawing correction filed on is a) appr | oved or b) disapproved by the | ne Examiner. | |
| 9. Note the attached Information Disclosure Statemen | | | |
| 10. | (-)(-) | · | |
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Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claim 29 made under 35 U.S.C. § 112, first paragraph for lacking written description.

Claims 1-12, 24-25 and 29 stand rejected under 35 U.S.C. § 101, for reasons of record, set forth in the office actions mailed on 03/09/04 and on 09/29/03, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants reiterate the same arguments presented in the response filed on 12/02/03, in that Example 7 of the instant specification discloses that the LICR2 of the instant application facilitates the activation of STAT factors. Applicants also argue that their post filing publication discloses that IL-10R-LICR-2 chimeric molecule was able to transduce a signal and caused phosphorylation of STAT1, STAT2, STAT3, and STAT5. Applicants further submit that since the roles of each of the STATs is known, it is not necessary to describe a particular STAT as being activated because the activation was generic and the activated molecules have a known function. Applicants also argue that the Examiner's argument that other molecules activate STATs is not relevant because there is more than one way to get a desired end. Also Applicants contend that the activation of STAT factors by the protein of the instant invention is an activity of said protein.

Specifically, this asserted utility is not specific or substantial. As was presented previously, such assays are generic and can be performed with many polynucleotide/polypeptide. The issue is not that many receptors may activate STAT factors, but that activating different STAT factors leads to different physiological processes. For example, activation of STAT proteins play different roles in normal physiological cell processes, such as proliferation, differentiation, angiogenesis, and apoptosis. STATS activation specificity within different cell lines depends on the specific interactions existing between the STAT proteins and their respective receptors. Thus, in the instant application, it is unclear what is the physiological end result once the protein of the instant invention activates STAT factors, is it involved in angiogenesis, apoptosis etc. Although LICR-2 may be involved in the activation of STAT factors in general, however, the instant specification does not teach the physiological role of said protein, i.e, the instant specification does not establish a nexus between the protein of the instant invention and a disease or a physiological condition.

JANET ANDRES
PRIMARY EXAMINER